NOV - 3 2000

510(K) SUMMARY

K00213

ConchaTherm 2000 Humidification System

Section 20

1.0 Date

April 13, 2000

2.0 Submitter

Hudson Respiratory Care, Inc.
27711 Diaz Road
Temecula, California 92590

3.0 Contact Person

Dana Houghton, CQA
Regulatory Affairs Specialist

4.0 Telephone

(909) 676-5611, ext. 1269

5.0 Proprietary Device Name

ConchaTherm 2000 Humidification System

6.0 Classification Name

Respiratory Gas Humidifier

7.0 Common Name

Respiratory Humidifier

8.0 Predicate Device

Fisher & Paykel Healthcare product number HC100, Heated Respiratory Humidifier and HC 325 Chamber, 510(k) number K915460

9.0 Device Description

The Hudson RCI ConchaTherm 2000 Humidification System will provide either cold passover humidification to a patient through the use of airflow through the humidification chamber, or heated humidification through the use of the Hudson RCI ConchaTherm 2000 Heated Humidifier in conjunction with the humidification chamber. The ConchaTherm 2000 has multiple heater settings (from 1-9), which will

provide heated humidification in the temperature range of 21°-26°C with a moisture output of up to 29 mg/L. Both the single patient use and the autoclavable humidification chambers provide for ease of disassembly, cleaning, and reassembly by virtue of the threaded bottom. The fill port at the top of the chambers is an added feature that provides for ease of filling.

The Hudson RCI ConchaTherm 2000 Humidification system is used to provide a flow of air through a length of polyolefin or polyester elastomer tubing and a PVC nasal mask to the patient, resulting in a positive pressure which helps to prevent blockage of the patient's airway that sometimes occurs through the relaxation of soft tissues in the back of the throat. Air circulates through water in the chamber, thereby picking up moisture, which is carried through the tubing and dispensed to the patient via a nasal mask. If the ConchaTherm 2000 Heated Humidifier is used, the water in the chamber is heated which, in turn, increases the amount of moisture in the airflow that is directed to the patient.

10.0 Intended Use

The ConchaTherm 2000 Humidification System is primarily intended for adult patients who need Continuous Positive Airway Pressure (CPAP) therapy, or Bi-level ventilation therapy, with a nasal or face mask. The System is placed between the gas source (CPAP generator, blower or ventilator) and the patient, and adds warmth and humidity to the air flow going to the patient. The added warmth and humidity lessons the drying effects that can occur from this type of therapy. It is not intended for use on patients whose upper airways have been bypassed.

12.0 Comparison of Technological Characteristics

Hudson RCI Respiratory humidifier is substantially equivalent to the predicate device in design, materials, chemical composition and function. Both units were tested to applicable standards for both patient temperature and moisture output utilizing both heated and cold passover operations. Additionally, testing was conducted in various operating conditions as outlined in the appropriate labeling.

13.0 Conclusion

Both the Hudson RCI ConchaTherm 2000 and the predicate device are able to provide continuous positive airway pressure (CPAP) or Bi-level positive airway pressure (BiPAP) therapy using heated humidification or cold passover humidification. Test results have demonstrated that the Hudson RCI ConchaTherm 2000 Humidification System is substantially equivalent in safety and effectiveness to the legally marketed predicate device with respect to its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2000

Ms. Dana Houghton
Hudson Respiratory Care, Inc.
27711 Diaz Road
P.O. Box 9020
Temecula, CA 92589

Re: K001213
ConchaTherm 2000 Humification System
Regulatory Class: II (two)
Product Code: 73 BTT
Dated: August 2, 2000
Received: August 11, 2000

Dear Ms. Houghton:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if Known):

Device Name: ConchaTherm 2000 Humidification System

Indications for Use: The ConchaTherm 2000 Humidification System is primarily intended for patients who need Continuous Positive Airway Pressure (CPAP) therapy, or Bi-level ventilation therapy, with a nasal or face mask. The System is placed between the gas source (CPAP generator, blower or ventilator) and the patient, and adds warmth and humidity to the air flow going to the patient. The added warmth and humidity lessens the drying effects that can occur from this type of therapy. It is not intended for use on patients whose upper airways have been bypassed.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001213

Prescription Use ✓ **OR** **Over-the-Counter Use**_____

Per 21 CFR 801.109

(Optional format 1-2-96)